DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

D1334B

August 20, 1997

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-40-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Vernon Loucks Jr., CEO
Baxter Healthcare Corp, Inc.
One Baxter Parkway
Deerfield, IL 60015

Dear Mr. Loucks:

During an inspection of the Deerfield, Illinois (designated complaint handling) facility of the Fenwal Division from June 13 to 26, 1997, Investigators Jeanne Morris and Chad Schmear determined the Fenwal Division of Baxter manufactures blood bags. Blood bags are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed the devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice Regulations (GMP) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to investigate complaints involving the possible failure of blood collection bags to meet any of their specifications or demonstrate that a similar complaint had already been investigated. There is not always information to support the conclusion drawn to close out a complaint based on a previous investigation. For example, Complaint USBF970528029 was closed out with a code attributing the mold growth to customer use of over-label, compromised foil pouch integrity, or anticoagulant leakage. There was no information in the complaint file to support this conclusion.

2. Failure to investigate complaints without documenting the reason no investigation was made. Our inspection found that at least 15 events were classified as "non-complaints" without documentation of the reason no investigation was made.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the enclosed Form FDA 483 issued to Mr. Joseph J. Tsiakals at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are

responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that Mr. Joseph J. Tsiakals submitted to this office a response, dated July 1, 1997, concerning our investigators' observations noted on the Form FDA 483. It appears that the response is adequate, therefore no export certificates will be denied for GMP reasons.

You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a later comprehensive follow-up inspection, and may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Based on your acceptable response to the FDA 483, no response is required to this letter.

Sincerely,

/S/

Raymond V. Mlecko
District Director

Enclosure

cc: Mr. Roberto Perez
President
Fenwal Division of Baxter Healthcare
One Baxter Parkway
Deerfield, IL 60015

cc: Mr. Joseph J. Tsiakals
Vice President
Fenwal Division of Baxter Healthcare
1627 Lake Cook Road
Deerfield, IL 60015